K113554

APR - 5 2012

510(k) Summary

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Device Information

Trade Name: CMI Implant IS System
Common Name: Endosseous Dental Implant
Classification Name: Implant, Endosseous, Root-Form
Product Code: DZE, NHA
Regulation Number: 21 CFR 872.3640
Date prepared: 4/3/2012

General Description

The CMI Implant IS System is a dental implant system made of titanium Grade s of ASTM F 67 intended to be surgically placed in the bone of the upper or lower jaw arches. The CMI Implant IS System is composed of submerged fixtures with straight & angled abutments. To cover all case of surgery, each component of dental implant set has various size and dimension.

1. Fixture

It is only part to be implanted into bone, and to provide connection of prosthetic devices or other components of a dental implant set with human body (mandibular or maxillary bone). There are two types of Fixtures, Submerged implant design and non-micro thread design.

The diameters of submerged implant design fixtures are 3.5/4.0/5.0/6.0/7.0/8.0mm and the lengths are 7.0/8.5/10.0/11.5/13.0/15.0 mm. The diameters of Non-Micro thread design fixtures are 3.5/4.0/4.5/5.0/5.5/6.0/7.0/8.0mm and the lengths are 7.0/7.3/8.5/10.0/11.5/13.0/15.0mm.

2. Cover Screw, Healing Abutment

: It is used to stop up hole of fixture to prevent inside of hole from being contaminated by germ and from being covered by teethridge during osseointegration.

: It is used to stop up hole of fixture to prevent inside of hole from being contaminated by germ and from being covered by teethridge for term of making upper prostheses and establishing proper emergence profile after osseointegration.

3. Abutment

It is intermediate component placed between the implant (fixture) and restoration (Crown, gold or ceramic) providing support. Device is made of gold alloy or unalloyed titanium which can be used coated with TiN or non-coated state. There are Cemented(Hex/non-Hex), Angled, SCRP, Solid, UCLA Gold/Plastic, Ball, and Temporary Abutment in this system.

The system is similar to the commercially available product based on the intended use, the technology used, the material composition employed and performance characteristics. IS System is made from pure titanium and the surface treatment is done with R.B.M.

Indication for use

The CMI Implant IS System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. IS System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. Also, implants with diameters larger than 5 mm are indicated for molar regions.

Device Description & Technological Characteristics

***The purpose of the device modification to purpose the variety of products for users' preference**

- Addition of Implant Fixture (non-micro thread type)
- Addition of the number of models according to the addition of sizes of Two IS Fixtures, Cover Screw, Healing Cap, Solid Abutment, Protective Cap, Cemented abutment, Cemented SCRP Abutment, Cemented non-Hex Abutment- Non Sterilized, UCLA Abutment, Ball Abutment, Temporary Abutment, and Combination Screw.
- Shelf-Life change : 3years →5yeaes

Materials

This device is manufactured from Ti G4 and Ti-6Al-4V ELI alloy following ASTM and ISO standards.

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Non-clinical test data

Fatigue testing was performed in accordance with ISO 14801 standard and risk analysis was performed in accordance with ISO 14971 standard.

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

* CMI Implant IS System (K090825)

Comparison to Predicate Devices:

The CMI Implant System have the same device characteristics as the predicate device, CMI Implant IS System (K090825), intended use, surface treatment, composition of material, general shape, structure and application method design are same. Comparisons have established that the subject device, CMI Implant IS System is substantially equivalent to the cleared Premarket Notification Device, CMI Implant IS System (K090825).

		Subject Device	**Predicate Device**
Product Name		CMI Implant IS System	CMI Implant IS System
510(k)		N/A	K090825
Manufacturer		neobiotech Co., Ltd.	neobiotech Co., Ltd.
Design		Submerged Implant design non-micro thread design	Submerged Implant design
Intended use		Identical to the predicate	for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.
Composition of Material		Titanium Grade 4 of ASTM F 67	Titanium Grade 4 of ASTM F 67
Device design	**Dia(Ø)**	3.5/4.0/4.5/5.0/5.5/6.0/7.0/8.0	3.5/4.0/5.0/6.0/7.0/8.0
Device design	**Length(L)**	7.0/7.3/8.5/10.0/11.5/13.0/15.0	7.0/8.5/10.0/11.5/13.0/15.0

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Surface treatment	RBM	RBM
Biocompatibility	Yes	Yes
Sterilization	Gamma Sterilization	Gamma Sterilization

Conclusion

The CMI Implant IS System has the same device characteristics as the predicate device, CMI Implant IS System (K090825). The intended use, surface treatment, composition of material, general shape, structure, and application method design are same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Neobiotech Company, Limited
C/O Ms. April Lee
Kodent, Incorporated
325 North Puente Street Unit B
Brea, California 92821

APR - 5 2012

Re: K113554
Trade/Device Name: CMI Implant IS System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 1, 2012
Received: March 7, 2012

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K113554

Device Name: CMI Implant IS System

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113554

Prescription Use _____x_____ AND/OR
Over-The-Counter _____

(Part 21 CFR 801 Subpart D)
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)